REDACTED VERSION – PUBLICLY FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LIMITED,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED,

Defendants.

Civil Action No. 04-171
CONFIDENTIAL
FILED UNDER SEAL

TEVA'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT

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I. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDING

This is a patent infringement action initiated by Glaxo following Teva's submission of an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j) to the Food and Drug Administration ("the FDA") for approval to market and sell a generic formulation of Glaxo's Zantac® oral solution, a brand-name drug covered by U.S. Patent No. 5,068,249 (the "'249 patent"). Glaxo has conceded that the '249 patent claims do not literally cover Teva's ranitidine oral solution because the patent claims require the inclusion of ethanol while Teva's formulation does not include ethanol.

Teva's opening brief support of its affirmative motion for summary judgment of non-infringement (D.I. 104) argues that Glaxo may not employ the doctrine of equivalents to expand the scope of its patent to include a ranitidine oral solution that does not contain ethanol. Teva alternatively argues that the doctrine of equivalents should not be available as a means to expand the scope of Glaxo's claims under the hypothetical claim analysis set forth in *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677 (Fed. Cir. 1990). Moreover, Teva argues that Glaxo has not met its burden of proof in any circumstance, given the lack of any proof that

performs all of ethanol in a ranitidine oral solution, or that stabilizes Teva's ANDA formulation in any manner.

Glaxo's Answering Brief, specifically including the declaration of Dr. Long, (D.I. 126) fails to establish a genuine issue of material fact sufficient to justify Glaxo's effort to expand the scope of its patent claims to include the use of in a ranitidine oral solution. Alternatively, Teva reiterates that Glaxo's infringement case suffers from a fatal lack of proof, even assuming the Court permits Glaxo some scope of equivalents.

II. SUMMARY OF THE ARGUMENT

Glaxo cannot, as a matter of law, employ the doctrine of equivalents to claim that the '249 patent is broad enough to cover Teva's generic oral solution.

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Glaxo convinced the Patent Office that it was entitled to a patent based on its argument that "only by the present invention" would one of ordinary skill in the art recognize the stabilizing benefits of ethanol in ranitidine syrup. (G 000206).[1] This central argument was in response to the Examiner's belief that the use of ethanol as a stabilizer was nothing but a design choice among other "known conventional excipients." (G 000200). Glaxo's arguments establish a clear and unmistakable surrender of any claim to any known conventional excipient other than ethanol in a ranitidine oral solution. Glaxo cannot now employ the doctrine of equivalents to recapture the use of another "known conventional excipient, namely, within the scope of its patent claims.

To obtain its patent, Glaxo also narrowed the claim limitation "ethanol" to avoid both enablement and prior art rejections from the Patent Office. The presumption of surrender set forth in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002) is therefore invoked. Glaxo must rebut the *Festo* presumption in order to be given an opportunity to broaden its claims here.

Glaxo has not, and cannot, rebut the *Festo* presumption by claiming its amendments were tangential to the use of in an aqueous ranitidine formulation. Glaxo amended its claims while acknowledging prior art formulations contained "lower aliphatic alcohols," including . Indeed, Glaxo made the key amendment at the same time it disclosed to the Examiner its British application, No. 2,120,938A, a reference disclosing aqueous ranitidine compositions that, according to Glaxo, were "formulated in water or organic solvents including a reference to lower aliphatic alcohols, optionally in admixture with water." (G000144).

is a lower aliphatic alcohol. Glaxo's amendments, narrowing its claims from a ranitidine formulation "also containing ethanol" to one with "a stabilizing effective amount of ethanol," were made to emphasize that its invention was the use of a stabilizing effect amount of ethanol

[1] As used in this brief, reference to documents with a "G" prefix refer to Docket Index No. 107, the Joint Claim Construction Chart For U.S. Patent No. 5,068,249.

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the only choice among many "lower aliphatic alcohols" used in aqueous ranitidine formulations at the time. Glaxo's amendments were made to avoid overlap with the prior art, which disclosed the use of other "lower aliphatic alcohols," in ranitidine formulations. Glaxo's amendments were not tangential to the scope of equivalents it now seeks.

Glaxo also has not rebutted the *Festo* presumption on the grounds that the stabilizing properties of in ranitidine formulations were not foreseeable at the time of its amendments. Rebutting the *Festo* presumption on such a basis requires an "objective inquiry, asking whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of amendment," not an inquiry of the inventor's actual state of mind prior to filing the patent application. *Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*, 356 F.3d 1348, 1353 (Fed. Cir. 2004) (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed. Cir. 2003)); *accord Amgen Inc. v. Hoechst Marion Roussel, Inc*, No. 05-1157, 2006 U.S. App. LEXIS 19799, *62 (Fed. Cir. Aug. 3, 2006)(finding patentee failed to rebut *Festo* presumption based on arguments similar to those made by Glaxo here). The operative inquiry here is whether one of ordinary skill in the art at the time of the amendment at issue "would have considered" the equivalent, not whether one of ordinary skill in the art in fact considered, tested, and definitively concluded that the equivalent was available. *Impax*, 356 F.3d at 1355-56 (examining the prior art and other available public references to conclude that Glaxo was aware of "potential" equivalents to the limitation at issue at the time of amendment and rejecting Glaxo's attempt to rebut a *Festo* presumption of surrender by claiming unforeseeability of the alleged equivalent). Dr. Long's explanation of what he meant by his lab book entries does not change the fact that Dr. Long, undeniably one of ordinary skill in the art, considered as a potential excipient in an oral ranitidine solution and furthermore considered the stabilizing properties of when selecting excipients to solve the stability problem presented by microbial contamination of Glaxo's syrups. Dr. Long's state of mind prior to discovery of his alleged invention is not relevant to the *Festo* inquiry.

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Alternatively, Dr. Long's declaration forecloses Glaxo's ability to assert that a hypothetical claim under the doctrine of equivalents broad enough to include Such a claim would not have been patentable under *Wilson Sporting Goods*. Setting aside the novel concept that a party can assert patent protection over the use of a commonly known excipient that the inventor alleges to have never invented or even considered, it is clear that the '249 patent's specification would not have enabled a claim to the use of Had Glaxo made such a claim, it would not have been allowed by the Patent Office due to a complete lack of enablement. Glaxo cannot now, through the doctrine of equivalents, assert patent protection over subject matter that, if claimed, would not have been allowed.

Assuming, *arguendo*, that this Court deems some range of equivalents to be appropriate, the Court still should grant Teva's motion. Glaxo has failed to set forth even a *prima facie* showing that the in Teva's formulation meets the claim term "ethanol" under the doctrine of equivalents. Glaxo has failed to prove that Teva's formulation meets ethanol serves in its ranitidine syrup. Moreover, the parties do not dispute that Teva's formulation uses the technology employed by Glaxo in one of its expired patents to maintain a specific pH level in its formulation to stabilize ranitidine.[2] Because Glaxo has not compared Teva's formulation with and without an admittedly easy or routine test, there is no reliable way for Glaxo to prove that contributes in any manner to the stability of Teva's formulation.

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III. STATEMENT OF THE FACTS

Both parties already have submitted detailed statements of fact in their respective moving briefs. Glaxo's Answering Brief, however, ignores the fact that the issued claims of the '249

[2] Teva does not admit that stabilizes ranitidine, as Glaxo contends. Teva recognizes that its formulation, in total, is sufficiently stable to obtain FDA approval for its claimed shelf life. Teva explained in its Answering Brief to Glaxo's Motion for Summary Judgment of Infringement that genuine issues of material fact prevent a finding as a matter of law on the question of whether is responsible for the stability of Teva's formulation. (D.I. 128 at pp. 22-25). Teva has not sought summary judgment on this ground.

patent stem from a central narrowing amendment of its original claims, made by Glaxo to overcome prior art in addition to curing the Examiner's rejections under § 112.

Glaxo initially sought a patent on an aqueous formulation of ranitidine "also containing ethanol." (G 000120). The Patent Office rejected this claim on the basis that it was not enabled under 35 U.S.C. § 112, and because the prior art disclosed ranitidine formulations with ethanol. (G 000132). Glaxo responded by amending its independent claims to read "a stabilizing effective amount of ethanol" in response to both rejections, submitting that "all the claims now present in the application are in full compliance with 35 USC 112 and are clearly patentable over the references of record." (G 000139-140)(emphasis added). In the same amendment, Glaxo disclosed and made "of record" an additional prior art reference, one of its own patent applications pending in the United Kingdom - Application No. 2,120,938A. (G 000144). This reference, by Glaxo's own description to the Patent Office, disclosed a formulation with ranitidine that "may be formulated in water or organic solvents including . . . lower aliphatic alcohols."[3] (G 000144).

While it is true that Glaxo's amendment was made in the context of the Examiner's first rejection under § 112, it is also clear that Glaxo's amendment was additionally made to emphasize that, unlike prior art ranitidine formulations "of record" that contained ethanol or other "lower aliphatic alcohols," Glaxo's invention was drawn to a "stabilizing" amount of only ethanol--not any other potential excipient. (G 000207; G 000139-140). Glaxo's myopic focus on only the Examiner's rejections based on 35 U.S.C. § 112 ignores the totality of circumstances surrounding its amendment and that it was also made to avoid prior art formulations disclosing "lower aliphatic alcohols" in aqueous formulations containing ranitidine.

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[3] is a lower aliphatic alcohol. (D.I. 105, Exhibit 1 at p. A005, ¶ 64) (Anderson 3/16/06 Report).

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IV. ARGUMENT

A. Glaxo Has Not Met Its Summary Judgment Burden To Show A Triable Issue On Whether Performs All Of The Functions Of Ethanol In An Oral Solution.

Glaxo has failed to prove that stabilizes Teva's ranitidine syrup at all, much less that it performs all of the same functions as ethanol in the same way to achieve substantially the same result. Recall that Glaxo's own expert, Dr. Anderson, opined in his expert report and confirmed in his deposition that in ranitidine syrup:

(D. I. 105, Exhibit 1 at A002, ¶40) (Anderson 3/16/06 Report). Dr. Anderson admitted that ethanol performs in ranitidine formulations, both as taught in the '249 patent, and as used in Glaxo's syrup. (D.I. 129, Ex. 17 at A134, Anderson Depo. p. 73)

Yet, Dr. Anderson presented no analysis, no testing, and no opinion on whether acts as a or whether in Teva's formulation. Indeed, the only evidence before this Court is that does not as it failed Dr. Long's early tests. (Long Dec. ¶ 14) (D.I. 126).

Furthermore, Glaxo cannot prove that stabilizes ranitidine in any manner because it has not conducted a controlled experiment to determine whether stabilizes Teva's formulation.[4] (D.I. 129, Ex. 17 at A135-136; Anderson Depo. pp. 197-198). Teva's formulation employs other ingredients in a manner that maintains a specific pH level in its formulation to stabilize of the formulation, technology employed by an expired Glaxo patent. Glaxo cannot prove otherwise.[5] Glaxo's expert admitted that such a test would be easy to

[4] Teva believes that such a controlled experiment should be incorporated into the definition of the claim term "stabilizing effective amount." *See* Teva's Markman brief. (D.I. 101).
[5] This is another key factual distinction between the case at bar and the *Pharmadyne* trial. In *Pharmadyne*, the district court explicitly noted that *Pharmadyne* had not presented evidence to

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perform. (*Id.*). And indeed, Dr. Hempenstall convinced the Patent Office that ethanol caused a surprising increase in stability of ranitidine in Glaxo's syrups with such a test by comparing the stability of ranitidine in a formulation both with and without ethanol. (G000209) ("Stability studies were carried out comparing this formulation with a formulation that was identical except that it did no contain ethanol."). Yet, Glaxo has not done even one simple comparison of Teva's formulation both with and without to prove its case here. Glaxo would prefer not to know whether truly has any stabilizing effect on Teva's formulation, or whether it simply is the pH as claimed in its earlier patent.

Regardless, both parties agree that the "triple identity" test set forth in *Graver Tank & Mfg. Co., v. Linde Air Products Co.*, 339 U.S. 605 (1950) and further defined in *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997) is the appropriate test to determine infringement under the doctrine of equivalents. Glaxo, however, incorrectly interprets the test.

Glaxo argues that both cases stand for the proposition that in the function-way-result test, the sole function at issue when determining equivalence is the "claimed function." This is not correct for two reasons. First, Glaxo's '249 patent does not claim a function it claims an ingredient ethanol. Had Glaxo meant to claim a function, it could have done so by use of a means-plus-function claim, as authorized by 35 U.S.C. § 112 ¶ 6. Such a claim could have explicitly claimed the function of substantially enhancing ranitidine. *See* 35 U.S.C. § 112 ¶ 6. However, none of Glaxo's claims are expressed in means-plus-function format. Glaxo's

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support a finding "that something other than acts as a stabilizer in the accuse product." *Pharmadyne*, 32 F. Supp. 2d 265, 291 (D. Mass. 1998). The opposite is true here, as Teva employs Glaxo's expired pH patent to stabilize its ranitidine syrup, which has nothing to do with As claimed by Glaxo in its expired British Patent No. 2,142,820, the "Padfield" reference, "the shelf life of aqueous based formulations containing ranitidine . . . may be significantly enhanced if the pH of the formulation is adjusted within the range of 6.5-7.5." (D.I. 105, Ex. 11 at A050, lines 19-21) (emphasis added). Teva admits it formulation falls within this pH range. (D.I. 99, Ex. 27 (Langer Decl.)("the buffering agents had to be selected to provide a final pH range of 6.5 to 7.5 in order to maintain the stability of Ranitidine.")).

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characterization of the '249 patent to suggest that there is a "claimed function" is a mischaracterization of the '249 patent.[6]

Second, the definition of "function" for the purposes of an equivalency analysis is much broader than Glaxo contends. *Graver Tank* and *Warner-Jenkinson* both state that "consideration must be given to the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform." *Graver Tank & Mfg. Co., v. Linde Air Products Co.*, 339 U.S. 605, 609 (1950); *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 25 (1997). The Court's statement here makes no mention of the "claimed function" and instead directs the analysis to the purpose in the patent. Here, to prove its case, Glaxo must show that has the same purpose, quality, and all intended functions of ethanol as an ingredient in a ranitidine oral solution.

The Federal Circuit has further distilled this concept from *Graver Tank's* holding. Where the patented product and the accused product differ by one ingredient, "it is appropriate for a court to consider in assessing equivalence whether the changed ingredient has the same purpose, quality, and function as the claimed ingredient." *Atlas Powder Company v. E.I. Du Pont De Nemours & Co. and Alamo Explosives Co, Inc.*, 750 F.2d 1569, 1579-80 (Fed. Cir. 1984) (emphasis added). "The operative definition for purposes of equivalency analysis is the intended function as seen in the context of the patent, the prosecution history, and the prior art." *Genentech, Inc. v. The Wellcome Foundation Ltd.*, 29 F.3d 1555, 1567 (Fed. Cir. 1994). Based on these holdings, the function-way-result test does not focus solely on the "claimed function,"

[6] To determine literal infringement under a means plus function claim, one must look to see whether the "claimed" function is present. *Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries, Inc.*, 145 F.3d 1303, 1308 (Fed. Cir. 1998)(citing *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987)). This is distinctly a different test than one for infringement under the doctrine of equivalents of a non-means plus function claim. *Id.* At 1310-11 (noting the differences between § 112 infringement and infringement under the doctrine of equivalents and specifically stating that that equivalents under § 112 "is an application of the doctrine of equivalents in a restrictive role, narrowing the application of broad literal terms.")(quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997)). The two analysis are different as should not be confused. In this case, the function to be examined is the function in the patented invention. *Graver Tank*, 339 U.S. at 609.

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but rather upon whether the ingredient at issue, and the qualities it has when combined with other ingredients, as well as the "function which it is intended to perform" in the patent. *Graver Tank*, 339 U.S. at 609.

As explained in Teva's moving brief, (D.I. 104 at pp. 37-38), Glaxo's expert has never analyzed whether acts as or as in a ranitidine oral solution, that Glaxo's own expert claims ethanol performs in ranitidine syrup. The only evidence is that does not have sufficient stabilizing properties and this evidence comes from Glaxo's own Dr. Long. (Long Decl. ¶ 14) (D.I. 126). This central lack of proof is fatal to Glaxo's infringement claim.

B. Glaxo's Repeated Argument And Submission Of Experimental Evidence To Distinguish Ethanol Above Other Known Excipients During Prosecution Establishes A Clear And Unmistakable Surrender Of The Use Of Other Known Excipients To Stabilize Ranitidine.

Throughout the entire prosecution of '249 patent, Glaxo manifested an objective and verifiable surrender of the use of any commonly available excipient but ethanol to stabilize ranitidine oral solutions. Glaxo's surrender began with its October 30, 1989, Amendment, narrowing Glaxo's pending claim from a syrup "containing ethanol" to a syrup with "a stabilizing effective amount of ethanol." (G 000139). This Amendment was filed at the same time Glaxo disclosed as prior art its own British application, UK Patent Application GB 2 120 938A, (the '938 Application") that disclosed ranitidine formulations using "lower aliphatic alcohols." (G 000144). Glaxo's contention that this amendment and the corresponding argument did not demonstrate Glaxo's effort to limit its invention to ethanol ignores the fact that Glaxo's reason for the amendment was "to avoid the prior art of record." The "prior art of record" included the use of "lower aliphatic alcohols." (Id.).

In a subsequent rejection, dated January 17, 1990, the Examiner remained unconvinced that even "a stabilizing effective amount of ethanol" was patentable, in light of another British reference disclosed by Glaxo. (G 000200). In light of this reference, the Examiner stated that

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Glaxo's claims were "insufficient to overcome the prior art without the aid of experimental data to show a definite improvement over" the prior art. (G 000200). The Examiner stated the use of ethanol "is considered merely to be a choice among known conventional excipients." (Id.) To prove that the use of ethanol, among the "known conventional excipients" was patentably distinct from the prior art, Glaxo presented the Hempenstall declaration. (G000208-211). Glaxo accompanied this declaration with the final (and ultimately persuasive) argument that knowledge of the use of ethanol to stabilize ranitidine is "provided only by the present invention." (G000206) (emphasis added). This argument plainly tells the public that Glaxo considered ethanol, not any other "known conventional excipient," to be the unique excipient that causes enhanced stability in its ranitidine syrup. This objective evidence invokes an argument-based estoppel against Glaxo, prohibiting expansion of its claims to include other known conventional excipients, including *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1378 (Fed. Cir. 1999). Glaxo's argument to the contrary is wrong.

C. Glaxo's Narrowing Amendments Invoke The *Festo* Presumption.

Glaxo's argument that the term "ethanol" was not narrowed during prosecution invites the Court to misapply the *Festo* methodology by confusing the scope of the subject matter surrendered with the question of whether an estoppel-invoking amendment occurred. The Supreme Court was clear that "[e]stoppel arises when an amendment is made to secure the patent and the amendment narrows the patent's scope." *Festo Corp.*, 535 U.S. at 736. As explained by the Federal Circuit on remand from the Supreme Court's 2002 decision, the first step of the inquiry is to determine whether "an amendment . . . has narrowed the literal scope of a claim." *Festo Corp.*, 344 F.3d at 1366 (citing *Pioneer Magnetics,Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1356 (Fed. Cir. 2003)). If there was a narrowing amendment, then the second step of the inquiry is to determine "whether the reason for that amendment was a substantial one relating to patentability." *Id.* Only during the third step does the court asses whether the alleged equivalent is within the scope of the subject matter surrendered by the narrowing amendment. *Id* at 1367.

The first two steps of the *Festo* methodology are satisfied here. First, the Federal Circuit has been clear that adding a new limitation to a pre-existing claim qualifies as a "narrowing amendment" for the purposes of assessing whether prosecution history estoppel applies. *Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1140 (Fed. Cir. 2004) ("That the addition of a claim limitation constitutes a narrowing amendment is manifest in the language of both *Warner-Jenkinson* and *Festo*"). Here, Glaxo's amendment of its patent claims from a syrup "containing ethanol" to a syrup with "a stabilizing effective amount of ethanol" unquestionably adds a new limitation to pre-existing claims, and is therefore a narrowing amendment. *Festo*, 535 U.S. at 736. Second, Glaxo made this amendment to both overcome a rejection under 35 U.S.C. § 112 and to overcome the prior art of record. (G 000140). This central amendment was therefore made for "substantial reasons relating to patentability," which satisfies the second step in the *Festo* methodology. A presumption of surrender is, therefore, invoked by the *Festo* methodology.

The third step of the *Festo* methodology addresses "the scope of the subject matter surrendered by the narrowing amendment." *Festo*, 344 F.3d at 1367. At the third step, the patentee (Glaxo) is required to rebut the presumption that it surrendered "the particular equivalent in question." *Id.* Glaxo, to meet this burden, must show that, at the time of the amendment in question, "one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Festo*, 344 F.3d at 1368.

Glaxo invites error into the *Festo* analysis by suggesting that the Court consider the third step (determining the scope of surrender) before it determines whether the first two steps (determining whether a narrowing amendment was made for reasons relating to patentability) have been met. This is not the law. That the parties have elected to address construction of the term "ethanol" separate from construction of the phrase "stabilizing effective amount" does not mean that "ethanol" was not narrowed by amendment. Glaxo's argument is creative, but it asks this Court to ignore every word in Glaxo's progressively narrowed claims but "ethanol." Glaxo

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then invites the Court, in error, to assume that since the term "ethanol" did not change form, there was no surrender of claim scope throughout the prosecution. Glaxo is wrong. Its claims were significantly narrowed for substantive reasons of patentability during prosecution, thereby invoking a presumption of surrender. It is now Glaxo's burden to prove that was not within the scope of that surrender, a burden it cannot meet here.

D. Glaxo's Narrowing Amendments Were Not Merely Tangential To The Use Of As An Excipient In Ranitidine Syrup.

As stated above, the third step of the *Festo* methodology shifts the burden to Glaxo to show that it could not have been expected to draft a claim to literally include the use of in its ranitidine syrup in October of 1989, when it made its narrowing amendment. *Festo*, 344 F.3d at 1368. Glaxo does not contend that any "shortcomings of language" prevented it from describing at the time of its amendments. To the contrary, Dr. Long's Declaration establishes without question that there were no "shortcomings of language" that could possibly be the reason "why the [Dr. Long] was prevented from describing the alleged equivalent when [he] narrowed the claim" here. *Festo Corp*, 344 F.3d at 1370. Indeed, Dr. Long clearly knew how to as an excipient in ranitidine oral solutions when he amended his claims.

Instead, Glaxo's first try at rebutting the presumption of surrender is to argue that its amendment "bears no more than a tangential relation to the equivalent in question." (D.I. 123 at p. 15) (citing *Festo*, 535 U.S. at 740). This analysis focuses on Glaxo's "objectively apparent reason for the narrowing amendment," which should be "discernable from the prosecution history record, if the public notice function of a patent and its prosecution history is to have significance." *Festo*, 344 F.3d at 1369. Glaxo attempts to alter the public record here by asserting the only reason it amended its claims was to respond to the examiner's "stated ground for rejection under § 112 that the amounts of the ingredients need to be stated in the claims." (Id.) The very text of Glaxo's October 1989 amendment, however, refutes this assertion. The Amendment objectively states, in

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the "remarks" following the amendment, that "all the claims now present in the application are in full compliance with 35 USC 112 and are clearly patentable over the references of record." (G000140)(emphasis added). It is objectively apparent that the amendment was done to both overcome the examiner's §112 rejection, and to demonstrate patentability over the prior art of record. Glaxo cannot revise this objective, public record by pretending some of it does not exist. Glaxo had two reasons for its amendment, one of which was to avoid its own prior art.

Glaxo, in error, also claims that it did not amend its claims to avoid prior art disclosing the use of other excipients in ranitidine solutions. (D.I. 123 at p. 15). This too is wrong. Glaxo's October 1998 amendment was made at the same time it disclosed its own British patent application, the '938 Application. (G 000144). The '938 Application, by Glaxo's own admission to the Patent Office, disclosed ranitidine formulations "formulated in water or organic solvents including a reference to lower aliphatic alcohols, optionally in admixture with water." (Id.) , the alleged equivalent, is a "lower aliphatic alcohol." (D.I. 105, Ex. 1 at p. A005, ¶ 64) (Anderson 3/16/06 Report). Glaxo's October 1998 Amendment was not tangential to the use of , a "lower aliphatic alcohol," in aqueous ranitidine formulations. Thus, Glaxo made the October 1998 Amendment to specifically avoid prior art ranitidine formulations using lower aliphatic alcohols, including . As stated by the Federal Circuit on remand from the Supreme Court's *Festo* decision, "an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim." *Festo*, 344 F.3d at 1369. Glaxo's 1998 Amendment was central to the allowance of its claims.

Moreover, Glaxo's reliance on the district court's opinion in *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 287 F. Supp. 2d 126 (D. Mass. 2003) is misplaced. On August 3, 2006, the Federal Circuit reversed the district court's decision in *Amgen* squarely on the issue of whether the patentee's amendment was tangential to the equivalent in question. *Amgen Inc. v. Hoechst Marion Roussel, Inc,* No. 05-1157, 2006 U.S. App. LEXIS 19799, *62 (Fed. Cir. Aug. 3,

2006)(attached as Ex. 32, A253-272).[7] The Federal Circuit's reversal focused on the patentee's efforts to rebut at *Festo* presumption on the basis that an amendment was "tangential" to the equivalent at issue. *Id.*

The alleged equivalent in *Amgen* used a hormone with an amino acid sequence occurring naturally in humans (165). *Id. at* *42. The asserted patent, however, claimed the same hormone with an amino acid sequence that does not naturally occur in humans (166). *Id.* The patentee relied on the doctrine of equivalents to prove its infringement claim. During prosecution, the patentee faced a double patenting rejection, to which the patentee responded with an amendment to differentiate the scope of its pending application from the claims of a prior patent it owned. *Id.* at *59-60. The prior patent it owned included within its scope the use of the hormone but without any mention of whether the hormone was human or non-human. *Id.* at *59-60. Indeed, the prior patent covered the use of the hormone with any amino acid sequence -- human or not. *Id.* The amendment at issue limited the scope of the pending application to claim only "a human...product having the...amino acid sequence." *Id.* The district court deemed the amendment to have been merely tangential to the equivalent in question. *Id.* at *7.

The Federal Circuit reversed the district court on this point. *Id.* The Federal Circuit held that the amendment was indeed made to avoid overlap between the claims of the prior patent, and that the amendment "may have been central to overcoming" the double patenting rejection. *Id.* at *61. The Federal Circuit therefore ruled that the amendment could not have been "tangential" to the alleged equivalent. *Id.*

An analogous amendment occurred in this case. Here, Glaxo amended its pending claims to avoid overlap with one of its prior patent applications that disclosed ranitidine formulations with "lower aliphatic alcohols," but not specifically limited to ethanol. (G 000139-145). Here,

[7] Teva also cited the district court decision in *Amgen* in its moving brief, but solely for the purpose of summarizing the general proposition that *Festo* held that a patentee may rebut the *Festo* presumption by showing one skilled in the art could not have drafted a claim to literally encompass the alleged equivalent. (D.I. 104 at p. 29). The Federal Circuit's reversal of *Amgen* did not upset this basic principle of law.

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like in *Amgen*, the amendment was made to avoid prior art that utilized a lower aliphatic alcohol in ranitidine formulations. As in *Amgen*, Glaxo's Amendment was not tangential to, but was central to Glaxo's desire to avoid overlap with ranitidine formulations containing "other aliphatic alcohols," such as Under the reasoning of the Federal Circuit in *Amgen*, Glaxo has failed to rebut the *Festo* presumption on the grounds that its amendment was tangential to the use of in ranitidine formulations.

E. Because A Person Of Ordinary Skill In The Art Would Have Considered As A Potential Stabilizing Excipient In Ranitidine Syrup, Glaxo Has Failed To Rebut The *Festo* Presumption On The Basis Of Unforeseeability.

Glaxo's alternative attempt to rebut the *Festo* presumption by claiming it did not foresee the use of in ranitidine formulations at the time of its October 1989 amendment also fails. To be foreseeable for the purposes of defeating a patentee's efforts to rebut the *Festo* presumption, one of ordinary skill in the art need only have been expected to "consider" the "potential" for the equivalent at issue at the time of the amendment. *Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*, 356 F.3d 1348, 1355 (Fed. Cir. 2004) (collecting references and concluding that Glaxo "was aware of these potential hydrogel equivalents" at the time it amended the claims at issue.). That the patentee did not test the equivalent before filing its application is of no moment.

In *Impax*, Glaxo attempted to establish that it did not foresee the alleged equivalent because it had not tested the equivalent for the purpose claimed in its pending application, just as it argues here. *Id.* at 1355. The *Impax* court found that even though Glaxo had not performed testing on the alleged equivalent, there was "considerable evidence that suggests Glaxo could have described" the alleged equivalent at the time its claims were amended, "if not earlier." *Id.* The *Impax* court, therefore, concluded "that ordinarily skilled artisans at the time would have considered" the equivalent at issue, and affirmed the district court's summary judgment on non-infringement against Glaxo. *Id.*

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Dr. Long's consideration of the effect of on the stability of ranitidine before patent application demonstrates that one of ordinary skill in the art would have also considered the effect of for the same purpose years later, when Glaxo amended its claims. Once Dr. Long learned that ethanol imparted increased stability to Glaxo's ranitidine syrup, it cannot be reasonably disputed that one of skill in the art would not have also considered for the same purpose. Indeed, as noted by the *Pharmadyne* court, was one of a limited number of alcohols approved for use in pharmaceutical compositions by the FDA at the time. *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265, 287, n. 22 (D. Mass. 1998).

Further, Glaxo's own expert in the *Pharmadyne* trial testified that of those excipients approved for use in pharmaceutical products, "would be a prime candidate for replacement of ethanol and for evaluation as to its potential for having the same stabilizing effect as ethanol." *Id.* (citing Wray Tr. at 830). Glaxo's expert also testified that because and ethanol have similar chemical structures and properties,

Id. In a paradoxical and surprising about-face, Glaxo now asserts the opposite to be true -- that one of skill in the art could not possibly have foreseen or even considered whether and ethanol might behave the same way when Glaxo's claims were amended.

Glaxo's effort to characterize the testimony of Professor Arthur Kibbe out of chronological context is misleading. (D.I. 123 at pp. 20-21). Dr. Long alleges he made his surprising discovery concerning the use of ethanol to stabilize ranitidine in October of 1986. (Ex. 33, A274-275, Long Tr. pp. 426-427, ll. 21-24). Professor Kibbe's acknowledgement that he would not have "started out" with the use of ethanol to enhance ranitidine stability in December of 1986 does not speak at all to what one of ordinary skill in the art (especially Dr. Long) would have considered three years later, when Glaxo amended its claims to avoid its own prior art during prosecution. Again, the relevant inquiry is what one of skill in the art would have

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considered at the time of amendment and thus already knowing the alleged invention. *Festo*, 535 U.S. at 740. The inquiry does not focus on what the inventor actually knew prior to when the inventor has not yet stumbled upon his invention.

Dr. Long's purported failure to conduct explicit tests before he filed his patent application to assess whether would impart stability to ranitidine syrup is of no moment. Just as in *Impax*, there is ample evidence in the record to establish that persons of ordinary skill in the art would have considered to be an equivalent excipient to ethanol in ranitidine oral solutions in October of 1989. As a result, Glaxo cannot rebut the *Festo* presumption on the grounds that would not have been foreseeable to one of ordinary skill in the art in October of 1989.

F. Dr. Long's Declaration Affirms That A Hypothetical Claim Including Would Not Have Been Patentable Under *Wilson Sporting Goods*.

Dr. Long's declaration alternatively establishes that a hypothetical claim literally including at the time Dr. Long filed his application would not have been patentable, had it been claimed. A claim interpretation that covers , therefore, is disfavored. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 749 (Fed. Cir. 1988). Assuming Dr. Long's declaration to be true for purposes of this motion, Glaxo could not have obtained patent protection for as a stabilizer of its syrup because the specification of the '249 patent contained no testing of as a stabilizer. Further, Dr. Long's declaration states that he did not foresee its use as a stabilizer at that time. (D.I. 126, Long Decl. ¶ 19). Under *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677 (Fed Cir. 1990), a court may assess the appropriateness of an equivalent by considering "a hypothetical patent claim, sufficient in scope to literally cover the accused product," and then determining whether "that hypothetical claim could have been allowed by the PTO over the prior art." *Id.*

As Teva explained in its opening brief, in a field of art that is not predictable (such as claims involving chemical reactions), the scope of an allowable claim is limited to only those

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aspects of the invention disclosed in an application. D.I. 104 at p. 36. (citing *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970) and *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005)). Here, there is no dispute that Glaxo did not include data or teaching in its patent concerning the use of to stabilize ranitidine. Dr. Long indeed claims he did not conceive of the use of to stabilize ranitidine at any time. (Long Decl., ¶ 19, D.I. No. 126). As such, Dr. Long did not provide an enabling disclosure for a claim covering as a stabilizer for ranitidine. A hypothetical claim claiming would have been rejected by the Patent Office under 35 U.S.C. § 112.

Under *Wilson Sporting Goods*, Glaxo cannot now use the doctrine of equivalents to expand the scope of its claims to include To do so would give Glaxo patent protection over subject matter it could not have otherwise lawfully obtained from the Patent Office in the first instance. This would directly contradict the very purpose of the doctrine of equivalents. *Wilson*, 904 F.2d at 684 (stating the doctrine "exists to prevent a fraud on the patent, *Graver Tank*... (internal citation omitted), *not* to give a patentee something which he could not lawful have obtained from the PTO had he tried."). Such a result would also grant Glaxo patent protection over subject matter that Dr. Long admits he did not conceive of and therefore did not invent. No party should be granted, through litigation, patent protection over subject matter it did not invent--especially when the result of such a grant would be to prevent entry of a generic pharmaceutical composition to the market.

G. The *Johnson & Johnston* Decision And Many Others Not Addressed By Glaxo Underscore The Critical Role That The Patent Office Performs In Determining Patent Claim Scope.

The Federal Circuit's analysis in *Johnson & Johnston Assocs. Inc. v. R.E. Service Co.*, 285 F.3d 1046 (Fed. Cir. 2002) affirms that applicants for a patent must afford the Patent Office the first opportunity to determine the scope of any patent claim. Judge Rader's concurring opinion, in particular, concisely states the rule of law Teva advocates: "[w]hen one of ordinary skill in the relevant art would foresee coverage of an invention, a patent drafter has an obligation

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to claim those foreseeable limits." *Johnson & Johnston Assocs., Inc. v. R.E. Service Co.*, 285 F.3d at 1057 (Rader, J. concurring). "In other words, the patentee has an obligation to draft claims that capture all reasonably foreseeable ways to practice the invention. The doctrine of equivalents should not rescue a claim drafter who does not meet this obligation and provide such notice." *Id.*

Teva also set forth other policy-based rules of law that support the conclusion that when inventors claim narrowly, courts also apply the doctrine of equivalents narrowly, if at all. *Sage Products, Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1424 (Fed. Cir. 1997) (affirming summary judgment of non-infringement and noting the case to be an example of "why the law restricts application of the doctrine of equivalents without further fact finding" in some cases); *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1311 (Fed. Cir. 1998) (noting, in the context of a means-plus-function equivalents analysis, that "there is no policy-based reason why a patentee should get two bites at the apple."). The Federal Circuit was clear in *Sage Products* that broadening narrowly drafted claims by use of the doctrine of equivalents may cause claim language to be "reduced to functional abstracts, devoid of meaningful structural limitations on which the public could rely." 126 F.3d at 1424. Glaxo does not even mention *Sage Products* or *Chiuminatta Concrete* in its Answering Brief.

Rather, Glaxo constructs a straw man to attack, focusing primarily on distinguishing the facts of *Johnson & Johnston* from its conduct. Contrary to Glaxo's argument, however, Teva does not "contradict itself by relying on" *Johnson & Johnston*. Teva simply notes that cases such as *Johnson & Johnston*, that penalize patentees for disclosing but not claiming known embodiments, present analogous facts and similar public policy-based justification for preventing Glaxo here from expanding its narrow claims to ethanol as a ranitidine stabilizer now to include as well. Glaxo's superficial response to the fundamental policy issues raised by Teva belies the weakness of its case.

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V. CONCLUSION

The Court should reject Glaxo's effort to expand the scope of its claims to include the use of as a stabilizing excipient in its patent claims. Regardless, Glaxo also has not proven that any claim of the '249 patent is infringed by Teva's formulation because it has not shown that performs of ethanol in an oral ranitidine solution. Glaxo has never compared Teva's formulation to the same formulation without It cannot, therefore, prove that causes the stability of Teva's formulation, as opposed to the pH of Teva's product.

By its attorneys:

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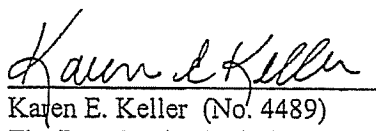

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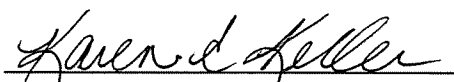

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